REMARKS/ARGUMENTS

The Claim Rejections Under 35 USC § 112 and 101

The claims are rejected under section 101 as allegedly not possessing utility because of the recitation of "prophylaxis," and are rejected under section 112 as allegedly not enabled because allegedly there is no utility. In sum, the only reasons provided for the rejections under these sections relate to the "utility" of the compounds in the claimed methods.

"A patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed." See *Fujikawa v. Wattanasin*, 39 USPQ2d 1895 (Fed. Cir. 1996), cited by *In re Fisher*, 76 USPQ2d 1225 (Fed. Cir. 2005). Applicants in the present case teach a substantial or practical utility and even provide data in support thereof, which the Office Action even acknowledges. Thus, for this reason alone, the rejections cannot stand.

The Office Action alleges that "applicants merely show inhibition, and that only under defined in vitro conditions, rather than prevention."

The data on pages 9-10 and in figure 1 show the inhibition of the androgen-dependent cell proliferation in LNCaP prostate cells (which are cancer cells). These data demonstrate the prevention of proliferation with the claimed combination. See, for example, figure 1 for the results. In the cells that were treated with R1881 (androgen) alone, the proliferation of the cells is clearly seen. Compare column 2 in figure 1 (R1881 treated cells), to column 1, which represents the data for cells with no treatment (control). The data sets from columns 3-6 represent cells that have been treated with the androgen R1881 and the second claimed component dienogest at various concentrations. The data demonstrate that a dose dependent prevention of the proliferation of the cells was achieved with the addition of dienogest, i.e., the higher the dienogest dose, the higher the prevention of cell proliferation. The cells that would have responded to R1881 by proliferation did not do so when the second component dienogest was present. This inhibition of proliferation that would have occurred otherwise is prophylaxis, i.e., prevention. For example, the data demonstrates that when 10 NM dienogest was added, the number of cells was significantly lower than when no dienogest was added (compare column 2 to column 6), and was indeed closer to the control than to the data where proliferation was not inhibited.

Additional data are also provided in support of the inhibition of prostate growth. See pages 12-13 and table 1. Prostate growth was induced by androgens and inhibited by dienogest in the claimed combination. The data in table 1 demonstrate that the testosterone propionate treated animals had higher prostate weights than both the intact control animals and the castrated control animals. See column 1 of the table. The claimed combination, e.g., when diegonest is administered in conjunction with testosterone propionate, demonstrates the inhibition of prostate growth, e.g., prostate growth was prevented by the claimed combination, which growth would have occurred otherwise if only testosterone propionate was administered. See data, for example, in the second to last row.

Such is more than adequate to not only set forth a substantial or practical utility, but also to support the same with biological data adequate to one of ordinary skill in the art to not doubt the utility of the claimed invention, and also to enable the same.

See, for example, *In re Fisher*, 76 USPQ2d 1225 (Fed. Cir. 2005), discussing *Cross v. Iizuka*, 224 USPQ 739 (Fed. Cir. 1985), *In re Jolles*, 206 USPQ 885 (C.C.P.A. 1980), and *Nelson v. Bowler*, 206 USPQ 881 (C.C.P.A. 1980), where

> the applicants disclosed specific pharmaceutical uses in humans for the claimed compounds and supported those uses with specific animal test data, *in vitro*, *in vivo*, or both. ... For example, in Nelson, the claimed prostaglandins could be used to stimulate smooth muscle or modulate blood pressure in humans as shown by both *in vivo* and *in vitro* animal data. Hence, the Jolles, Nelson, and Cross courts concluded that the claimed pharmaceutical compounds satisfied the specific and substantial utility requirements of §101.

Applicants here, as in the cases discussed above, disclosed specific pharmaceutical uses, and have provided *in vivo* (animal data on pages 12-13) and *in vitro* (LNCaP prostate cells data on pages 9-10) data in support thereof all reasonably correlated to the end use. Thus, the specific and substantial utility requirements of §101 are satisfied.

The Office Action also alleges that the data is in "defined ... conditions." However, such is not a shortcoming of the data. Any data provided in any application or research paper would necessarily be under a certain set of defined conditions. The experiments provided in the specification were designed to support the claimed invention, and they do.

The Office Action additionally alleges that "nowhere in the specification do applicants define what they experimentally consider as prevention." This allegation is incorrect. While the specification does not explicitly provide a "definitions" section, it clearly teaches to one of ordinary skill in the art what is the subject and scope of the invention. Additionally, the data demonstrate the activity of claimed combinations and provide further guidance to one of ordinary skill in the art in understanding what was invented.

No allegations were made regarding the enablement rejection other than that the rejection is made since there is no utility. Thus, for the reasons provided above, the enablement rejection too should be withdrawn.

Applicants, although not necessary here, provide some comments on the enablement rejection.

A specification disclosure which "contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (1971). "The PTO must have adequate support for its challenge to the credibility of applicant's statements of utility". (The quoted statement was made in the context of enablement, i.e., the how-to-use requirement of the first paragraph of section 112.) See also *In re Bundy*, 209 USPQ 48 (1981). The only relevant concern of the Patent Office should be over the truth of assertions relating to enablement. The first paragraph of section 112 requires nothing more than objective enablement. See *In re Marzocchi, supra.*

The Office Action has not established any basis to doubt objective enablement or provided support for establishing that one of ordinary skill would doubt the objective truth of the asserted utility, which is enabled by the specification. Merely, the adequacy of the data presented in the specification appeared to have been questioned. Thus, the rejections therefore were improper under *In re Marzocchi*.

Moreover, there is no indication that one of ordinary skill in the art would have questioned the effect of the drugs in view of the disclosure (e.g., the data in the specification) and the state of the art. See *Rasmusson v. Smithkline Beecham Co.*, 75 USPQ2d 1297 (Fed. Cir.

2005).

Relevant to the present case is also the holding of the Federal Circuit in *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1441 (Fed. Cir. 1995), stating that

> usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful can be well before it is ready to be administered to humans. If the courts were to require Phase II testing in order to prove utility for pharmaceutical inventions, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Applicants provided adequate support and evidence to establish utility and to enable the claimed invention. Reconsideration is respectfully requested.

The Claim Rejections Under 35 USC § 103

The Office Action clearly and explicitly interprets the term "prophylaxis" in the claims to mean "prevention" when making the sections 101 and 112 rejections, which is what the claims are explicitly directed to, and which is consistent with applicants' arguments in the last reply prior to this newfound interpretation by the Office Action. Nevertheless, the Office Action interprets the same term in the same claims to mean "treatment" when maintaining the prior art rejections.

During prosecution a claim term should be given its "broadest reasonable meaning" by the PTO. See *In re Cortright,* 49 USPQ2d 1464 (Fed. Cir. 1999). However, using such "broadest reasonable meaning" does not give a license to the PTO to interpret a single term in various inconsistent ways in an effort to make/uphold various rejections. Such goes beyond the "broadest reasonable meaning" standard.

Moreover, interpreting the same term in the same claim to have different meanings is inconsistent and confusing. It is in the interest of both the applicant and also the public to have a clear prosecution record, so that all will be able to use the prosecution history, among other things, to understand the scope of the claims. Giving claims their broadest reasonable

construction "serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified." See *In re Yamamoto*, 222 USPQ 934 (Fed. Cir. 1984). A claim term being interpreted in multiple ways for purposes of being able to reject a claim for multiple reasons does not serve the above purposes.

Under the proper construction of the term, i.e., so, that the term "prophylaxis" means what it explicitly states, the prior art rejections cannot be upheld for reasons already argued in the last reply, which is incorporated herein by reference.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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